April 26, 2018

Olympus Winter & Ibe GmbH
% Mr. Dolan Mills
Senior Specialist, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K180200
Trade/Device Name: ESG-300, APU-300, Pressure Reducer, MAPC Probes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 21, 2018
Received: March 22, 2018

Dear Mr. Mills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180200

Device Name

Electrosurgical Generator ESG-300 with Accessories

Indications for Use *(Describe)*

ESG-300: The electrosurgical generator ESG-300, in conjunction with electrosurgical accessories and ancillary equipment, is intended for cutting and coagulation of tissue in open surgery, laparoscopic surgery and endoscopic surgery. For monopolar argon plasma coagulation (MAPC) of tissue, the electrosurgical generator is intended to be used with a compatible Olympus argon plasma coagulation unit to deliver ionized argon gas.

Accessories:

APU-300: The argon plasma coagulation unit and its accessories, in conjunction with a compatible Olympus electrosurgical generator and monopolar argon plasma coagulation (MAPC) probes, are intended to deliver ionized argon gas for monopolar argon plasma coagulation of tissue.

Pressure Reducer (accessory of APU-300): The pressure reducers are accessories and must only be used in conjunction with the compatible argon plasma coagulation unit APU-300. Observe the instructions for use of the compatible argon plasma coagulation unit APU-300 regarding: intended use/ contraindications/ user qualifications/ environment of use/ compatible equipment

MAPC probes: The single use and flexible monopolar argon plasma coagulation probes, in conjunction with a compatible Olympus argon plasma coagulation unit and a compatible Olympus electrosurgical generator, are intended to deliver ionized argon gas for monopolar argon plasma coagulation of tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

2.1 General Information

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany
Establishment Registration Number: 9610773

Official Correspondent: Dolan Mills
Regulatory Affairs
Olympus Surgical Tech. America
Gyrus ACMI, Inc.
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Phone: (901) 373-0236
Establishment Registration No. 3003790304

Date Prepared: April 17, 2018

2.2 Device Identification

Proprietary name:

HF Generator:	Electrosurgical Generator ESG-300
Argon Plasma Unit:	APU-300
Argon Plasma Probes:	MAPC probes
Device Classification name:	Electrosurgical cutting and coagulation and accessories
Regulation Medical Specialty:	General & Plastic Surgery
Regulations Number:	21 CFR 878.4400
Regulatory class:	Class II
Product code:	GEI

2.3 Predicate Device

The proposed electrosurgical generator ESG-300 and accessories is considered substantially equivalent to the following legally marketed devices:

Primary Predicate Device	Manufacturer	510(k) No
ESG-400	Olympus Winter & Ibe GmbH	K141225

Table 2.1: Identification of primary predicate device

The following secondary predicates for monopolar argon plasma coagulation (MAPC) modes only have been chosen for substantial equivalence discussion in terms of safety and effectiveness.

Assigned components of the subject device	Reference Predicate Device	Manufacturer	510(k) No
ESG-300 (monopolar argon plasma coagulation modes only)	ERBE ESU Model VIO 300 D with Accessories	Erbe USA, Inc.	K083452
APU-300 with accessories	ERBE VIO APC (Model 2) with Accessories	Erbe USA, Inc.	K024047
MAPC probes	ERBE APC Integrated Filter Probes and Adapter	Erbe USA, Inc.	K060183

Table 2.2: Identification of secondary predicate device

2.4 Product Description

2.4.1 Electrosurgical generator

The subject device ESG-300 is a reusable, non-sterile electrosurgical generator that features different monopolar and bipolar cutting and coagulation modes. In combination with the compatible argon plasma coagulation unit APU-300, it features monopolar argon plasma coagulation modes. The maximum output power is 120 W.

The front panel of the proposed ESG-300 features a touch screen GUI (graphical user interface) that displays the current settings of the chosen output mode, the connection status of accessories and peripherals connected to the electrosurgical generator. Soft keys are integrated into the GUI to switch between the output sockets, to enter the Menu in order to edit settings/ procedures (e.g. create/ edit user-defined settings/ procedures), to edit preferences (e.g. select language, touch tone control, output volume, or brightness) and to show service options (e.g. software version identifier, for service and maintenance purposes) or to assess user-defined settings and procedures.

The subject device ESG-300 with accessories is a class II medical device under the regulation number 878.4400 and the product code GEI – “Electrosurgical cutting and coagulation device and accessories“. Regulation Medical Specialty: General & Plastic Surgery.
It is compliant with FDA recognized consensus safety standards as listed in section III, Appendix III - Standard Conformity and Test Reports.

2.4.2 Accessories

The electrosurgical generator can be used in conjunction with the compatible Olympus argon plasma coagulation unit and its accessories as well as the monopolar argon plasma coagulation (MAPC) probes. The single use MAPC probes only will be provided in sterile condition.
The front panel of the argon plasma coagulation unit APU-300 features the Argon socket (to connect a compatible MAPC probe), a purge button (to purge the system with argon gas) and the power switch.
The single use MAPC probes are offered in three different beam types, length and outer diameter each. The plug is proprietary to the APU-300.

2.5 Indications for Use

2.5.1 Electrosurgical generator

The ESG-300, in conjunction with electrosurgical accessories and ancillary equipment, is intended for cutting and coagulation of tissue in open surgery, laparoscopic surgery and endoscopic surgery. For monopolar argon plasma coagulation (MAPC) of tissue, the electrosurgical generator is intended to be used with a compatible Olympus argon plasma coagulation unit to deliver ionized argon gas.

2.5.2 Accessories:

Argon Plasma Coagulation Unit (APU-300):

The argon plasma coagulation unit and its accessories, in conjunction with a compatible Olympus electrosurgical generator and monopolar argon plasma coagulation (MAPC) probes, are intended to deliver ionized argon gas for monopolar argon plasma coagulation of tissue.

Pressure Reducer (accessory of APU-300):

The pressure reducers are accessories and must only be used in conjunction with the compatible argon plasma coagulation unit APU-300.
Observe the instructions for use of the compatible argon plasma coagulation unit APU-300 regarding: intended use/ contraindications/ user qualifications/ environment of use/ compatible equipment

MAPC probes:

The single use and flexible monopolar argon plasma coagulation probes, in conjunction with a compatible Olympus argon plasma coagulation unit and a compatible Olympus electrosurgical generator, are intended to deliver ionized argon gas for monopolar argon plasma coagulation of tissue.

2.6 Technological Characteristics

The ESG-300 has the same intended use and technological characteristics as the primary predicate device ESG-400.
Various instruments can be connected to the monopolar and bipolar sockets. Because the PK modes of the primary predicate device (K141225) are not integrated in the ESG-300, the flare out detection is not applicable. The basic design philosophy of the User Interface (UI) and GUI flow chart concept is identical, except for the special ESG-400 amendment in regards to the PK instruments.

2.6.1 Output modes in comparison to the primary predicate device ESG-400

In comparison to the primary predicate device the following output modes are available:

Subject Device: ESG-300	**Primary Predicate Device: ESG-400 (K141225)**
PureCut	PureCut
Blend Cut	Blend Cut
PulseCut slow	PulseCut slow
PulseCut fast	PulseCut fast

N/A	FineCut
N/A	PureCut

Table 2.3: Monopolar Cut Modes

Subject Device: ESG-300	**Primary Predicate Device: ESG-400 (K141225)**
SoftCoag	SoftCoag
PowerCoag	PowerCoag
ForcedCoag	ForcedCoag
SprayCoag	SprayCoag

Table 2.4: Monopolar Coagulation Modes

Subject Device: ESG-300	**Primary Predicate Device: ESG-400 (K141225)**
BipolarCut	BipolarCut
N/A	SalineCut
N/A	PK PureCut
N/A	PK SoftCut
N/A	PK LoopCut
N/A	PK MorceCut

Table 2.5: Bipolar Cut Modes

Subject Device: ESG-300	**Primary Predicate Device: ESG-400 (K141225)**
RFCoag	RFCoag
AutoCoag	AutoCoag
BiSoftCoag	BiSoftCoag
N/A	SalineCoag
N/A	HardCoag
N/A	FineCoag
N/A	PK Coag
N/A	PK SoftCoag
N/A	PK AutoCoag

Table 2.6: Bipolar Coagulation Modes

The range of output waveforms is identical but the power levels are decreased in comparison to the FDA cleared ESG-400 electrosurgical generator, K141225.

2.6.2 Monopolar argon plasma coagulation output modes in comparison to the secondary predicate devices

Additional Monopolar argon plasma coagulation modes were implemented exclusively for the argon plasma coagulation in conjunction with dedicated Olympus accessories.

Subject Device: ESG-300	**Secondary predicate device: ERBE ESU Model VIO 300 D (K083452)**
ForcedArgon	Forced APC
PulsedArgon Slow	Pulsed APC (Effect 1)
PulsedArgon Fast	Pulsed APC (Effect 2)
SmartArgon	Precise APC

Table 2.7: Monopolar Argon Plasma Coagulation Modes

The range of output waveforms is identical in comparison to the FDA cleared ERBE ESU Model VIO 300 D, K083452.

2.7 Substantial Equivalence

Substantial equivalence is demonstrated by acknowledged verification/validation methodologies. The subject devices have equivalent technology, performance, dimensions and materials. The differences to the primary predicate device ESG-400 are:

- only one monopolar socket, no universal socket, vertical alignment of the output sockets
- to be used only in conjunction with a double pedal footswitch
- no PK instruments incorporation
- Monopolar argon plasma coagulation in conjunction with dedicated Olympus accessories
- does not enable the user to select the effect of the output modes
- GUI modifications (additional strings, languages, sounds, screens, windows)

Regarding the additionally implemented monopolar argon plasma coagulation modes, a secondary predicate device and its required accessories have been chosen, because of their specific output modes. For both the substantial equivalence is demonstrated by acknowledged verification/validation methodologies. The subject device has equivalent technology and performance in respect to the compared modes.

2.8 Performance Data

The following performance data were provided in support of the substantial equivalence determination. All standards applied are FDA recognized international standards.

The data was prepared in accordance with the FDA guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff, issued on August 15, 2016. The guidance was followed for all relevant sections.

2.8.1 Biocompatibility testing

The ESG-300 and its accessories APU-300 and pressure reducer do not contain components that come directly or indirectly in patient contact. Biocompatibility testing according to ISO 10993 for these components is not required.
Biocompatibility testing of the MAPC probes accessories has been successfully conducted according to ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing. Additionally, the FDA guidance “Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” was followed.
Testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization

The patient contacting device is considered external communicating, tissue/bone/dentin, for a duration of less than 24 hours.

2.8.2 Electrical safety and electromagnetic compatibility (EMC)

The design of the ESG-300 with accessories complies with recognized standards as listed in section 2.10.

The FDA guidance "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices", CDRH July 11, 2016 has been followed.

2.8.3 Thermal Safety

The design of the ESG-300 with accessories complies with recognized standards as listed in section 2.10.

2.8.4 Animal Studies

Not applicable.

2.8.5 Clinical Studies

Clinical studies were not conducted for this submission.

2.8.6 Software

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005). The device software is considered a "Major Level of Concern".

2.8.7 Performance Testing Bench

To demonstrate substantial equivalence Olympus considered the following subject device aspects in regards to the predicate devices within the design validation:

1. Performance and validation tests incorporated the same range of waveform outputs and power levels.
2. During the validation testing the waveforms and tissue effects were compared directly between the subject and predicate device.

Bench testing supports the claim of substantial equivalence to the predicate devices. The validation plan specifies modes, instruments and test protocols/plans for tissue effects and electrical waveforms. Beside tissue effects, the waveforms of the generators were compared. For all modes the tests demonstrated comparable tissue effects and electrically comparable waveforms.

The following non-clinical and preclinical tests were conducted:
1) non-clinical (electrical, dimensional, functional, biocompatibility, stability)
2) preclinical (simulated use) evaluation and testing of tissue effects and thermal safety

Non-clinical: Basic safety and performance testing was performed in accordance with IEC standards. In addition, verification and comparison bench studies were conducted to evaluate the functional performance.

Stability: Sterile samples were subjected to accelerated aging to confirm that the disposable devices maintain functionality and continue to meet specifications over time. The results of the accelerated age testing demonstrate that the device will be

stable for the stated shelf-life. In addition, real time age testing will confirm the results of the accelerated age testing. Samples were also subjected to environmental conditioning and ship testing.

Preclinical: Evidence obtained from preclinical simulated use studies demonstrate that the device performs substantially equivalent to the predicate device in relevant aspects associated with usability, tissue effects, and thermal effects. For simulated use testing, three clinically relevant tissue types were evaluated in all applicable modes: porcine muscle for endoscopic procedures, porcine liver for open procedures and porcine kidney for laparoscopic procedures. In accordance with FDA Guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, the thermal damage of the tissue due to the HF current was measured in terms of size (length, width and depth) of the thermal coagulation zone. The tissue effects testing included quantitative and qualitative assessment. Furthermore, each test included the minimum, default and maximum intensity settings. All modes were compared to the predicate. Where the minimum or maximum intensity settings of the test and predicate device differed in terms of output wattage by specification the closest applicable settings were chosen.

In order to exclude variations due to the instrument, the tissue effect was probed with the subject and predicate generators and the same instruments. A representative selection of HF instruments was made that cover the broad spectrum of applications.

These comprehensive validation bench tests support equivalence to the predicate device. Testing confirmed that comparable tissue effects could be achieved for applicable modes of operation with the three tissue types. Therefore, comparison testing does support that the subject device is substantially equivalent to and is as safe and effective as the legally marketed predicate device.

Usability and user interface was also assessed according to the risk management plan. The assessment was based on Olympus predecessor product. Use-related hazardous situations were assessed and risk mitigation measures in terms of usability design for safety were defined. The residual risk was evaluated as acceptable.

Risk analysis was carried out in accordance with established internal acceptance criteria based on ISO 14971:2007.

2.9 Reprocessing, Sterilization and Shelf Life

Required cleaning, disinfecting and drying procedures are described in the instructions for use. Reprocessing of the single use MAPC probes is not applicable. Sterilization of the MAPC probes is performed according to ISO 11135 and packaging conforms to ISO 11607-1. The EtO sterilization cycle has been validated.
A sterility assurance level (SAL) of 10^{-6} was reached during validation and will be used for routine sterilization in compliance with regulations in force for sterile medical devices.

The EtO residuals are within the limits after tunnel degassing time.
Shelf Life testing was conducted, including performance testing and package integrity testing, to support a shelf life of 1 year for the MAPC probes.

2.10 Applied standards

Standard No.	Standard Title	FDA-Recognition no + date
AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	19-4 07/09/2014
IEC 60601-1-2 Ed. 4.0 b: 2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8 06/27/2016
IEC 60601-1-8 Ed. 2.1: 2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	5-76 08/05/2013
AAMI ANSI IEC 60601-2-2 Ed. 5.0: 2009	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories	6-229 08/05/2013
IEC 62304 Ed. 1.1: 2015	Medical device software - Software life cycle processes	13-79 04/04/2016
IEC 60601-1-6 Ed. 3.1: 2013	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89 06/27/2016
ISO 14971 Second edition 2007	Medical devices - Application of risk management to medical devices	5-40 08/20/2012
AAMI ANSI ISO 10993-1 2009/(R) 2013	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-156 07/26/2016
ISO 11135 Second Edition 2014	Sterilization of health-care products - ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices.	14-452 04/04/2016
ISO 11607-1 2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]	14-454 01/27/2015

Table 2.8: Applied standards

2.11 Conclusion

The performance data support the safety of the device and demonstrate that the subject devices comply with the recognized standards as specified.

In summary, we believe the ESG-300 with accessories is substantially equivalent with the predicate devices with respect to the general design approach, function, and the intended use. The ESG-300 with accessories raises no new concerns of safety or effectiveness when compared to the predicate devices.